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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

(SAN FRANCISCO DIVISION)

HELEN ARONIS, individually and on behalf of those similarly situated,

Plaintiffs,

vs.

MERCK & CO., INC.; SCHERING PLOUGH CORPORATION; SCHERING CORPORATION; SCHERING PLOUGH HEALTHCARE PRODUCTS, INC.; SCHERING-PLOUGH BIOPHARMA CORPORATION; SCHERING-PLOUGH HEALTHCARE PRODUCTS SALES CORPORATION, inclusive,

Defendants.

Case No: C 08 0348 SC

CLASS ACTION COMPLAINT FOR EQUITABLE RELIEF INCLUDING RESTITUTION AND DAMAGES; DEMAND FOR JURY TRIAL

Plaintiff, HELEN ARONIS, alleges, for herself individually, and on behalf of a class of similarly situated persons, against defendants MERCK & CO., INC., SCHERING PLOUGH CORPORATION, SCHERING CORPORATION, SCHERING PLOUGH HEALTHCARE PRODUCTS, INC., SCHERING-PLOUGH BIOPHARMA CORPORATION, and SCHERING-PLOUGH HEALTHCARE PRODUCTS SALES CORPORATION, inclusive, as follows:

JURISDICTION AND VENUE

1. The Federal District Court has jurisdiction over this action in that, pursuant to 28 U.S.C. 1332(d), minimal diversity exists as between plaintiffs and defendants, the action has been pleaded as a class action, and the amount in controversy exceeds the sum or value of $5,000,000.00, exclusive of interest and costs. None of the causes of action stated herein have been assigned or otherwise given to any other court or tribunal.

2. California has jurisdiction over Defendants, and each of them, in that, each is registered to and are in fact doing business within the State of California, and otherwise maintain requisite minimum contacts with the State of California.

3. Venue is proper in this District under 28 U.S.C. sections 28 U.S.C. 1391(a), (b) and (c), 28 U.S.C. section 1407 and 15 U.S.C. section 22 in that, inter alia, defendants and each of them do substantial business in the State of California and within this Federal Judicial District, advertise and market in this District, achieve a substantial percentage of their California sales within this District, and have made misrepresentations, and engaged in false and misleading, fraudulent, unfair business practices, and engaged in a common pattern and generalized practice of concealment and omission with respect to the quality and the performance attributes and benefits of prescription drug Vytorin all to the detriment of and injury to California purchasers of Vytorin including those within this District so as to subject them to in personam jurisdiction in this District.

PLAINTIFF

4. At all times herein relevant, plaintiff HELEN ARONIS was an individual residing in the County of Sacramento, State of California.

5. Plaintiff ARONIS has taken Vytorin since 2004.

6. Plaintiff brings this action as a class action. In this regard, plaintiff acts not only for himself but as representative of a class of similarly situated individuals who fall within the description of the Vytorin **CLASS** as defined and set forth in Paragraph 25, infra.

DEFENDANTS

7. Defendant MERCK & CO., INC. is a Delaware Corporation doing business in

the State of California who was responsible for and otherwise engaged and participated in the design, testing, investigation, approval for sale, manufacture, packaging, marketing, advertising, distribution, promotion and sale of the prescription drug Vytorin in the State of California.

8. Defendants SCHERING CORPORATION, SCHERING PLOUGH CORPORATION, SCHERING PLOUGH HEALTHCARE PRODUCTS, INC., SCHERING-PLOUGH BIOPHARMA CORPORATION, and SCHERING-PLOUGH HEALTHCARE PRODUCTS SALES CORPORATION (hereinafter "SCHERING-PLOUGH Defendants") are corporations registered to and/or doing business in the State of California who were responsible for and otherwise engaged and participated in the design, testing, investigation, approval for sale, manufacture, packaging, marketing, advertising, distribution, promotion and sale of the prescription drug Vytorin in the State of California.

9. Plaintiff is informed and believes and thereon avers that defendants, and each of them, were at all times herein mentioned the parents, subsidiaries, joint venture and/or marketing participants, partners, agents, servants, affiliates, relations, or employees of each of the other defendants and were at all times herein mentioned acting within the course and scope of said relationship, and acting with the consent and knowledge of, or in consort with, each other defendant.

10. Defendants, and each of them, came together for the purposes of and engaged in overt acts in furtherance of an implied and/or express agreement to engage in the unlawful and continuing course of conduct which, as set forth with greater factual particularity in Paragraphs 12-20, infra, violated, inter alia, California's UCL and Consumer Legal Remedies Act.

GENERAL ALLEGATIONS

11. Plaintiff ARONIS was prescribed and began taking Vytorin sometime in 2004. Since that time, plaintiff has consistently purchased Vytorin prescriptions and used Vytorin. Her co-pay per prescription for Vytorin, is a sum she is informed and believes is well in excess of the co-pay for generic Zocor (Simvistatin), resulting in a loss of money and

damage due to her purchase of Vytorin in excess of $100.00.

ZOCOR

12. Zocor is a drug developed and patented by defendant Merck. Zocor was first approved for and sold in the United States in or about November 1997. Zocor falls within the classification of drugs generally referred to as "statins." Statins generally and Zocor specifically is an inhibitor of HMG-CoA reductase which lowers cholesterol. The intended health benefit of statin drugs generally and Zocor specifically is: (1) to reduce the risk of total mortality by reducing coronary heart disease death, (2) to reduce the risk of non-fatal myocardial infarction and stroke, and (3) to reduce the need for coronary and non-coronary revascularization procedures.

13. Defendant Merck was wildly successful in its marketing and sale of Zocor. By 2004, annual sales were in excess of five billion dollars world-wide. Merck was keenly aware of the impending expiration of its patent on Zocor on June 23, 2006. Merck recognized that competing sales of generic Zocor, Simvistatin, would undermine the substantial revenue and profit stream the drug had generated for Merck for years. In an effort to maximize Zocor's value, defendant Merck sought out ways to continue its ability to exploit the use of the well-known Zocor in some patentable form.

ZETIA

14. Zetia is a drug developed and patented by the SCHERING-PLOUGH Defendants. Zetia was first approved for and sold in the United States in or about November 1997. Zetia is in a class of lipid lowering compounds which selectively inhibit the intestinal absorption of cholesterol. Zetia lowers cholesterol levels in users, with the expectation that by lowering cholesterol Zetia has the positive health benefit of arresting and slowing the development of artherosclerotic disease, and therefore cardiovascular injury and mortality.

15. Hurt, inter alia, by the expiration of its patent rights on its very successful allergy drug, Claritin, in or about 2002, the SCHERING-PLOUGH Defendants were reeling from poor financial results. They were aggressively seeking out ways to improve the

revenue stream and profitability of their lesser well known drugs such as Zetia.

VYTORIN

16. In or about 2004, Merck and the SCHERING-PLOUGH Defendants entered into a joint marketing agreement to develop market and sell a combination drug comprised of Zocor and Zetia to be called Vytorin. It was each company's hope that this new combination drug would be competitive with Lipitor in an exploding cholesterol-lowering drug market which, according to Merck, would be worth 21 billion dollars world-wide in 2004. Merck press releases represented that Merck planned to persuade doctors of the advantages of Vytorin over Lipitor and persuade them to switch their patients to Vytorin before the expiration of its Zocor patent in 2006. Relying on studies which purported to demonstrate that the Vytorin combination drug lowered cholesterol more than Zocor alone, but, plaintiff is informed and believes, without any support or evidence of any resulting meaningful health benefit to be derived therefrom by users, Vytorin was approved for sale by the FDA on July 23, 2004.

17. Marketed and advertised aggressively as a superior alternative to statins including Lipitor in terms of its positive health benefits, Vytorin vaulted to a third place position in sales of cholesterol lowering drugs in 2005, its first full year of sales. So successful was Vytorin that, according to the SCHERING-PLOUGH Defendants, sales for the first half of 2007 exceeded $2.4 billion dollars.

THE ENHANCE STUDY

18. The ENHANCE study was a multinational, randomized, double-blind, active comparator trial commenced by Merck and the SCHERING-PLOUGH Defendants undertaken around the time of Vytorin's FDA approval. The study was designed to use digitized single frame ultrasound technology to study and evaluate the health benefit of Vytorin versus Zocor in terms of preventing or minimizing the development of atherosclerotic disease. 720 participants, all of whom had been identified as HeFH (familial hyperlipidemia) patients, were involved. 357 received Vytorin. 363 received Zocor alone. The study collected carotid and femoral artery ultrasound images to study the effects on plaque development.

19. ENHANCE was commenced in 2004 and concluded in March 2006. The data and its implications in terms of the health benefits of Vytorin versus Zocor were available to Merck and the SCHERING-PLOUGH Defendants and could have been disclosed by March of 2006.

20. Instead of disclosing the damaging results, Merck and the SCHERING-PLOUGH Defendants repeatedly failed and refused to disclose the ENHANCE study data and results. Amid growing concern, complaints and skepticism as to the reasons for the delay from cardiologists around the world, defendants refused to disclose the ENHANCE data and results, blaming difficulties in analyzing the data as the source of the delay. Defendants failed to list the ENHANCE study on the U.S. federal government website clinicaltrials.gov which is supposed to have records of **all** clinical trials, and listed ENHANCE on that website, claiming oversight, in late 2007, only after media reports identified defendants' "oversight." Only after being threatened to action by the formal commencement of an investigation by the House of Representatives' Committee on Energy and Commerce did defendants first disclose the devastating results of the ENHANCE study in the form of a brief abstract submitted to the American College of Cardiology.

21. The ENHANCE results confirmed no health benefit from the use of Vytorin versus now generic Zocor. In fact, said study pointed to an adverse health consequence of Vytorin use versus Zocor to the extent that study images measured increases in plaque thickness in the Vytorin users in excess of those taking Zocor -- suggesting that Vytorin accelerated the development of atherosclerotic disease in patients in comparison to those taking Zocor alone. Evidence supported this adverse consequence of Vytorin use. Specifically, cardiovascular death and non-fatal myocardial infarction were twice as likely with Vytorin, with the incidence of stroke equal between users of Vytorin and Zocor.

22. Plaintiff and the **CLASS** aver that defendants, and each of them, promoted, sought and obtained approval for, marketed, advertised and sold Vytorin representing that it had health benefits superior to Lipitor, Zocor, Simvistatin, and other cholesterol lowering drugs fraudulently and deceitfully, when in fact defendants had no evidence of any such

superior benefits and knew that Vytorin had no such superior health benefits. Even after the ENHANCE study confirmed a lack of benefit **and** potential adverse health consequences resulting from the use of Vytorin versus the much cheaper statin drug Zocor (Simvistatin) alone, defendants continued to reap enormous profit from the sale of a potentially harmful combination drug, accomplishing this wrongful success by concealing what the ENHANCE data and results confirmed unequivocally and, which, if published, would have destroyed the market for Vytorin.

23. As a result of Defendants' unfair practices, inequitable conduct and their concealments and omissions, the putative **CLASS**, including plaintiff, were prescribed, purchased, and took Vytorin, to their monetary loss and damage.

24. Plaintiff and the **CLASS** have lost money and suffered monetary damages as a result. Specifically, **CLASS** members paid a readily ascertainable amount for drugs which were of no benefit or health advantage to them, which sum was in excess of the cost of more reasonably priced and more effective alternatives, e.g. Zocor alone. **CLASS** members have or will suffer further monetary loss and damage until said members cease paying for and taking Vytorin and Zetia.

CLASS ALLEGATIONS

25. Plaintiff seeks to maintain this action and each cause of action thereof as a **CLASS** action pursuant to F.R.C.P. 23 (b)(1), (b)(2) and (b)(3), on behalf of himself and on behalf of a group of similarly situated persons. The **CLASS** is defined as:

California purchasers of VYTORIN.

26. This action has been brought and may properly be maintained and certified as a **CLASS** action because:

(a) The questions and issues of law or fact raised herein are of a common or general interest, affecting a large **CLASS** of individuals and the public at large;

(b) The **CLASS** consists of a sufficiently large group of individuals, believed to exceed 50,000 members, and is so large that it is impractical to

present all members of the **CLASS** before the Court as individual plaintiffs. Plaintiff is informed and believe that the identity of class members is readily ascertainable from various sources including prescription and other distribution records and, if necessary, notice by publication in California;

(c) The questions of law or fact common to the **CLASS** are substantially similar and predominate over those questions affecting only specific members of the **CLASS**.

(d) The **CLASS** is united by a community of interest in obtaining appropriate equitable relief including restitution, damages, and other available relief designed to redress the wrongful conduct of Defendants.

(e) Plaintiff is a member of the **CLASS**, and his claims are typical of the **CLASS.**

(f) Named Plaintiff will fairly and adequately represent the claims of the **CLASS**, and protect the interests of the **CLASS** without exercising personal interest or otherwise acting in a manner inconsistent with the best interests of the **CLASS** generally.

(g) Named plaintiff has retained attorneys experienced in the litigation of class and representative claims, and in the area consumer protection litigation who have agreed to and will responsibly and vigorously advocate on behalf of the **CLASS** as a whole.

(h) Without **CLASS** certification, the prosecution of separate consumer actions by individual members of the **CLASS** would be impracticable and financially implausible given the complexity of the issues involved and the enormous resources and adverse motivations of defendants, and create a risk of repetitive, inconsistent and varying adjudications. This would have the effect of establishing incompatible standards of conduct for Defendants, discouraging the prosecution of meritorious but small claims, and/or result in adjudications which would be dispositive of the interests of other **CLASS**

members not parties to the adjudication, or otherwise substantially impair the ability of **CLASS** members to protect their rights and interests.

(i) Defendants have acted or refused to act on grounds generally applicable to the **CLASS**, thereby making the award of equitable relief and/or damages appropriate to the **CLASS** as a whole.

(j) The class action procedure is superior to other methods of adjudication, and specifically designed to result in the fair, uniform and efficient adjudication of the claims presented by this complaint. This **CLASS** action will facilitate judicial economy and preclude the undue financial, administrative and procedural burdens which would necessarily result from a multiplicity of individual actions.

FIRST CAUSE OF ACTION

(Unfair Business Practices)

27. Plaintiff and the **CLASS** incorporate by reference all preceding paragraphs and allegations as if fully set forth herein.

28. California Business & Professions Code section 17200 precludes unfair competition, i.e., the employment of any unlawful, unfair or fraudulent business acts or practices; and any unfair, deceptive, untrue or misleading advertising violative of Ca. Bus. & Prof. Code section 17500. (hereinafter collectively "UCL"). Said prohibition extends to any act, omission or conduct engaged in or affecting the rights of consumers within the State of California.

29. In engaging in and otherwise participating in the design, testing, investigation, approval for sale, manufacture, packaging, marketing, advertising, distribution, promotion and sale of the prescription drug Vytorin in the State of California, without any basis or justification to present Vytorin as safe, effective or beneficial to those to whom the drug was marketed and sold as opposed to statins such as Zocor (Simvistatin), defendants and each of them engaged in unfair, fraudulent and unlawful conduct within the meaning of Ca. Bus. & Prof. Code section 17200, et seq., and section 17500. Moreover, defendants failed and

continued to fail since at least 2004 to disclose and to conceal new and additional information which reaffirmed the potential harm, and lack of health benefits, associated with the use of Vytorin and Zetia versus the statin Zocor. Despite increasing and inexcusable awareness of said drugs' ineffectiveness and propensity to harm and worsen the medical condition of those for whom said drugs were marketed and sold, defendants continued to sell Vytorin to their significant but wrongful financial benefit.

30. The aforementioned conduct is unlawful within the meaning of the UCL in that, inter alia, said conduct violates Ca. Civil Code section 1750, et seq. (hereinafter "CLRA") to the extent that defendants and each of them represented by statement and omission that Vytorin and Zetia: (a) had characteristics, uses or benefits that it did not have in violation of Section 1770(e) of the CLRA; and (b) was of a particular standard, quality or grade when it was of another in violation of 1770(g) of the CLRA.

31. The aforementioned conduct is fraudulent, and false and misleading, within the meaning of the UCL in that defendants and each of them misrepresented by omission the supposed health benefits of Vytorin over statins and failed to disclose the lack of health benefit, and potential adverse consequence associated with the use of Vytorin and Zetia as opposed to statins like Zocor, to California users of Vytorin and Zetia.

32. Defendants' conduct is unfair within the meaning of the UCL in that the the alleged consumer injury is substantial, creating an unreasonable risk for monetary and potentially physical injury to Vytorin users. There is no counterveiling benefit to consumers as opposed to statins including Simvistatin, any contrary argument is rendered implausible given the data and results of the ENCHANCE study, and defendants concealment of same.

33. Were it not for the aforementioned unfair competition of defendants, the **CLASS** would not have purchased or continued to purchase Vytorin to their significant monetary detriment, and to defendants' unjust and inequitable enrichment.

34. The **CLASS** has and will continue to suffer injury in fact and lose money as a direct result of Defendants' unfair competition in that each paid a readily ascertainable sum to purchase and take Vytorin, and will continue to do so until taken off the drugs.

35. As a result of Defendants' unfair competition, the **CLASS** is entitled to appropriate equitable relief including injunctive relief, and available monetary relief in the form of restitution (including fluid recovery once certified as a class action). Plaintiffs are also entitled to recover award of attorneys' fees and costs in connection with the prosecution of this action.

SECOND CAUSE OF ACTION

(Unjust Enrichment)

36. Plaintiff incorporates by reference all preceding paragraphs and allegations as if fully set forth herein.

37. Defendants have been, and continue to be, unjustly enriched, to the detriment of and at the expense of the **CLASS** members, as a result of its unlawful and/or wrongful pattern of conduct directed against the **CLASS** as a whole and its resulting collection of benefits including, inter alia, **CLASS** members' payments for Vytorin and Zetia, such that Defendants' retention of such payments is inequitable.

38. Defendants have unjustly benefitted through the unlawful and/or wrongful collection of, inter alia, payments for Vytorin and Zetia and continue to so benefit to the detriment and at the expense of **CLASS** members.

39. Accordingly, Defendants should not be allowed to retain the proceeds from the benefits conferred upon it by the **CLASS** members, who seek disgorgement of Defendants' unjustly acquired profits and other monetary benefits resulting from its unlawful conduct, and seek restitution and/or rescission for the benefit of the **CLASS** members, in an equitable and efficient fashion to be determined by the Court.

40. The **CLASS** members are entitled to the imposition of a constructive trust upon Defendants such that their enrichment, benefit and ill-gotten gains may be allocated and distributed equitably by the Court to and/or for the benefit of **CLASS** members.

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THIRD CAUSE OF ACTION

(Concealment and Failure to Disclose)

41. Plaintiff incorporates by reference all preceding paragraphs and allegations as if fully set forth herein.

42. As set forth in paragraphs 12-22, supra, of this Complaint, in pursuing a generalized and common pattern of omission and concealment directed against the **CLASS** devised to fraudulently extract monies including excessive co-pays from each **CLASS** member, defendants failed to disclose and concealed the true facts that Vytorin provided no health benefit, was ineffective for the purpose for which it was intended to benefit the health and welfare of **CLASS** members, and was in fact counterproductive and potentially harmful to **CLASS** members' cardiovascular health and well-being. Defendants engaged in the acts of omission and concealment intentionally and with knowledge of the ineffectiveness and dangers associated with the use of Vytorin versus statins such as Zocor (Simvistatin), and continued after March of 2006 to omit and conceal these material facts for the specific purpose of continuing to receive and profit handsomely from billions of dollars in revenue from the sale of these drugs. Defendants had no reasonable basis to believe that these drugs were effective or of any meaningful heath benefit to the **CLASS**.

43. The **CLASS** was genuinely, foreseeably, and innocently ignorant of the defendants' aforesaid acts and concealment. The **CLASS** was induced by and reasonably relied upon the material omissions of fact of defendants in purchasing and using Zetia.

44. As a result of defendants' omission and concealment, each member of the **CLASS** paid a specific and readily ascertainable amount of money to defendants, and each of them, to which defendants were not entitled. The **CLASS** is entitled to recover the amounts it was wrongfully induced to pay along with interest thereon.

45. As a result of the omissions and concealment herein alleged, the **CLASS** is entitled to and hereby request an accounting of all proceeds received and profits made, and the imposition of a constructive trust over said reimbursements and profits derived therefrom.

46. In performing the acts described herein, while omitting and concealing the

true facts which would have rendered their marketing and sale of Zetia and Vytorin impossible, and with knowledge of the true performance characteristics of Vytorin and Zetia, defendants willfully, intentionally, recklessly and in conscious disregard of the rights and safety of specifically identified persons of need, pursued their injurious but wildly profitable fraud against the **CLASS** as a whole, entitling the **CLASS** to an award of punitive damages.

RELIEF REQUESTED

WHEREFORE, the **CLASS** prays judgment against defendants, and each of them, as hereinafter follows:

ON THE FIRST CAUSE OF ACTION:

1. Equitable and/or injunctive relief as appropriate;
2. Monetary relief including restitution (fluid recovery when certified as a class);
3. Attorneys' fees; and
4. Penalties.

ON THE SECOND CAUSE OF ACTION:

1. Equitable relief in the form of restitution and disgorgement of profits;
2. Consequential and general damages; and
3. Imposition of a constructive trust over the revenues of sale and resulting profits received as a result of defendants' wrongful conduct.

ON THE THIRD CAUSE OF ACTION:

1. Compensatory and special damages according to proof; and
2. Punitive damages.

ON ALL CAUSES OF ACTION:

1. Attorneys Fees;
2. Costs of suit;
3. Interest; and
4. Such other and further relief as the court deems proper.

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DEMAND FOR JURY TRIAL

Plaintiff demands trial by jury of each cause of action set forth in this complaint and the issues in this matter.

Dated: January 22, 2008

CLAYEO C. ARNOLD
A Professional Law Corporation

By: _____
KIRK J. WOLDEN
Attorney for the **CLASS**